

APR 23 2001

K010508

(3)

510(k) SUMMARY

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DATE: January 31, 2001

CONTACT PERSON: Linda K. Dillon
Chuck Lakel

TRADE NAME OF DEVICE: Pasco MIC and MIC/ID Panels

COMMON NAME: Antimicrobial Susceptibility Test

CLASSIFICATION NAME: Class II Antimicrobial Susceptibility Test Microbiology
Panel #83

SUBSTANTIAL EQUIVALENCE:

In review of previous 510(k) notifications for the Pasco MIC and MIC/ID panels (most recently: K001953, August 10, 2000 RE: Amoxicillin; K001887, August 9, 2000 RE: Ampicillin; K001721, August 4, 2000 RE: Clarithromycin; K001612, July 18, 2000 RE: Linezolid; K001516, July 12, 2000 RE: Moxifloxacin; K992853, November 4, 1999 RE: Cefdinir; K992726, November 3, 1999 RE: Synercid (non-fastidious); K992717, November 2, 1999 RE: Synercid; K992646, October 19, 1999 RE: Penicillin; K992647, October 19, 1999 RE: Erythromycin; K992593, October 14, 1999 RE: Chloramphenicol; K992562, October 13, 1999 RE: Ceftriaxone; K992568, October 14, 1999 RE: Cefotaxime; K992507, October 18, 1999 RE: Trovafloxacin; K992546, October 12, 1999 RE: Meropenem; K992420, September 27, 1999 RE: Sparfloxacin; K992296, September 21, 1999 RE: Vancomycin; K992297, September 3, 1999 RE: Levofloxacin; K992143, September 16, 1999 RE: Clindamycin; K992108, September 3, 1999 RE: Cefepime; K992076, August 30, 1999 RE: Cefuroxime; K992059, August 30, 1999 RE: Imipenem; K992077, September 3, 1999 RE: Ofloxacin; K991925, August 20, 1999 RE: Amoxicillin/Clavulanic Acid; and K946126, January 17, 1995 RE: Detection of resistant pneumococci), the FDA has determined the Pasco panels to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DESCRIPTION OF THE DEVICE:

Varying concentrations of antimicrobial agents (usually in two-fold dilutions) are dispensed into the Pasco panels and the panels are then frozen. Panels are thawed prior to use, inoculated with

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the test organisms, incubated the traditional 16-24 hours and panels are then observed for visible growth or color changes as described in the package insert.

The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC). Changes in pH and production of specific metabolites from growth in biochemical substrates are interpreted as described in the package insert for conventional tubed media.

INTENDED USE FOR THE PASCO MIC AND MIC/ID PANELS:

PASCO MIC AND MIC/ID PANELS are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement or category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms.

SUMMARY/CONCLUSION OF SUBSTANTIAL EQUIVALENCE TESTING:

Using routine manufacturing processes, antimicrobial agents were diluted in Cation Adjusted Mueller Hinton Broth to concentrations required for the Initial Screen Test and the Phenotypic Confirmatory Test (described in the NCCLS document M100-S11, Table 2A). For test purposes, additional concentrations other than those described in the M100-S11 were also included. Data presented here include the following antimicrobial concentrations- Cefpodoxime (16-0.015 mcg/ml), Ceftazidime (128-0.03 mcg/ml) and Aztreonam (64-0.015 mcg/ml) for the Screen Test and Cefotaxime (64-0.015 mcg/ml) and Ceftazidime (128-0.03 mcg/ml) with and without Clavulanic Acid (4 mcg/ml) for the Confirmatory Test. Test panels containing Cefpodoxime at 16-0.015 mcg/ml, Ceftazidime at 128-0.03 mcg/ml and Aztreonam at 64-0.015 mcg/ml for use for the Initial Screen Test and Cefotaxime at 64-0.015 mcg/ml and Ceftazidime at 128-0.03 mcg/ml with and without Clavulanic Acid at 4 mcg/ml for use in the Phenotypic Confirmatory Test (NCCLS M100-S11, Table 2A).

Testing included 113 strains (78 ESBL-positive and 35 ESBL-negative) of *Klebsiella pneumoniae*, *K. oxytoca* and *E. coli* of various origin, which were genotypically or phenotypically characterized as ESBL producers or non-ESBL producers. Reproducibility testing was performed internally at Pasco and at two external sites (CDC and UCLA) and ESBL-positive challenge strain testing was conducted at Massachusetts General Hospital.

The Initial Screen and Confirmatory Tests in Pasco panels demonstrated a Sensitivity of 100%. The 95% confidence interval for the Screen and Confirmatory Test is 100-100%. The Screen Test Specificity is 87.6% and the Confirmatory Test Specificity is 99%.

A minimum of 25 QC results for the two NCCLS recommended QC strains, which included *E. coli* ATCC 25922 (ESBL-negative) and *K. pneumoniae* ATCC 700603 (ESBL-positive) were acceptable for each of the four sites.

The results of the reproducibility, challenge strain testing and QC performance testing supports Substantial Equivalence as outlined as applicable in the FDA draft document "Review Criteria for Assessment of Antimicrobial Susceptibility Devices" Draft, March 8, 2000.



APR 23 2001

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Linda K. Dillon
Technical Manager
12750 West 42nd Ave.
Wheat Ridge, CO 80033

Re: 510(k) Number: K010508
Trade/Device Name: PASCO MIC and MIC/ID Panels
Inclusion of ESBL Screen Test
Regulation Number: 866.1640
Regulatory Class: II
Product Code: LTT
Dated: January 31, 2001
Received: February 21, 2001

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

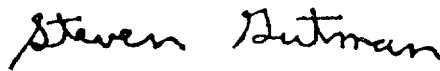
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010508

Device Name: PASCO MIC and MIC/ID Panels
Inclusion of ESBL Screen Test

Indications For Use:

Pasco MIC and MIC/ID panels are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement of category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms. The antimicrobial agents cefpodoxime, ceftazidime and aztreonam, currently included in Pasco Gram-Negative panels, will be used to screen for ESBL production as well. The Pasco ESBL Screen Test is used to detect potential Extended Spectrum *B*-lactamase (ESBL) production of *Klebsiella pneumoniae*, *K. oxytoca* and *E. coli* isolates.

This 510(k) notification is for the use of the following antimicrobial concentrations included in Pasco panels for the purpose of screening for potential ESBL-producing strains.

Cefpodoxime	4 - 1 mcg/ml
Ceftazidime	16 - 1 mcg/ml
Aztreonam	16 - 4 mcg/ml

Strains of *Klebsiella pneumoniae*, *K. oxytoca* and *E. coli* may be screened for potential ESBL production using the screening breakpoint of 1 mcg/ml for the screen agents cefpodoxime and ceftazidime along with the higher concentrations of the screening agent aztreonam (16, 8 and 4 mcg/ml) included in Pasco Gram-Negative panels. *Klebsiella pneumoniae*, *K. oxytoca* and *E. coli* isolates with MICs ≥ 2 mcg/ml for either cefpodoxime or ceftazidime or an MIC of ≥ 4 mcg/ml for aztreonam should be considered suspicious for ESBL production. Prior to reporting MIC results as resistant for penicillins, cephalosporins and aztreonam, confirmatory testing should be performed.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010508

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)